



## Valvular Heart Disease

### THE EVEREST II REALISM CONTINUED ACCESS STUDY: EFFECTIVENESS OF TRANSCATHETER REDUCTION OF SIGNIFICANT MITRAL REGURGITATION IN SURGICAL CANDIDATES

Oral Contributions

West, Room 2010

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Session Title: Valvular Heart Disease: Year in Review, Functional MR, E-Clip Updates and MR in the Context of AS

Abstract Category: 32. Valvular Heart Disease: Therapy

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*Authors: Saibal Kar, D. Lim, Richard Smalling, Brian Whisenant, Chidambaram Rammohan, Peter Fail, Michael Rinaldi, James Hermiller, Howard Herrmann, Robert Kipperman, John Williams, Carlos Ruiz, William Gray, James Slater, Neil Weissman, Elyse Foster, Ted Feldman, REALISM Continued Access Trial Investigators, Cedars-Sinai Medical Center, Los Angeles, CA, USA*

**Background:** The EVEREST II REALISM Continued Access study (REALISM) is a prospective, multi-center, continued access study to collect data on the “real world” use of the MitraClip device in both high and non-high surgical risk patients. Enrollment in the non-high risk arm was initiated in January 2009 at the conclusion of the EVEREST II Randomized Controlled Trial (RCT) to allow patients continued access to the therapy. Enrollment was closed in April 2011. As of April 2012, all 272 non-high risk patients completed 1-year follow-up. Complete 1-year safety and effectiveness results as well as a comparison with the EVEREST II RCT will be presented.

**Methods:** Patients with 3+ or 4+ mitral regurgitation (MR) were enrolled. Pre- and post-procedure and follow-up echos for all patients were evaluated by an independent core lab. Acute procedural safety results at 30 days and survival at 12 months are summarized. Effectiveness results, defined by reduction in MR and improvement in clinical outcomes, based on changes in NYHA Class and quality of life are reported.

**Results:** Although eligibility criteria were similar between the EVEREST II RCT and the non-high risk arm of the REALISM study, patients enrolled in the latter were older and more co-morbid. Mean age of patients enrolled in non-high risk REALISM was 74 ±11 years vs. 67±13 in EVEREST II RCT. Degenerative MR was present in 69% and functional MR in 31% compared to 73% and 27%, respectively in EVEREST II RCT. Freedom from mortality at 12 months was 91.0% (EVEREST II RCT was 93.7%). Importantly, freedom from mitral valve surgery at 12 months was 90.1% which was improved from 80% in the EVEREST II RCT. Consistent with the EVEREST II RCT, a majority of patients experienced MR reduction to ≤2+ at 12 months with associated LV remodeling. In addition, 92% of patients in NYHA Class I/II at 12 months and scores for the physical and mental components of the SF-36 improved between baseline and 12 months.

**Conclusion:** The MitraClip procedure resulted in significant and durable improvements in MR severity, LV remodeling, and clinical outcomes, and the required rates of mitral valve surgery post-index procedure in the non-high risk REALISM were lower than those observed in the EVEREST II RCT.